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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Aaron T. Timperman

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EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/784,393	Applicant(s) TIMPERMAN, AARON T.	
	Examiner William H. Beisner	Art Unit 1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3 and 5-40 is/are pending in the application.
- 4a) Of the above claim(s) 13-35 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-12, 36-38 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 13-35 and 39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/8/04. Note new claim 39 is withdrawn in view of its dependency from withdrawn claim 18.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 5-12, 36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 6,007,690) in view of Wang et al.(Rapid Communications in Mass Spectrometry).

The reference of Nelson et al. discloses a microfluidic device that includes an inlet channel (66); a reaction channel (enrichment channel, 62) and solid supports (3) in communication with the reaction channel and capable of concentrating a charged analyte produced by a reaction in the reaction channel.

While the reference of Nelson et al. discloses that the reaction channel (enrichment channel, 62) may be used as a microreactor for protein digestion (See column 4, lines 43-67), the reference does not specifically disclose that enzyme is located in the channel.

The reference of Wang et al. clearly discloses that it is conventional in the art to provide enzyme (agent) within a reaction channel on a microfluidic device (See Figure 1 and related disclosure).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the enrichment channel (62) of the reference of Nelson et al. with an enzyme for the known and expected result of providing an art recognized means for protein digestion so as to provide a microreactor as suggested by the reference of Nelson et al.

With respect to the specifics of the membrane employed of claims 1 and 3, the reference of Nelson et al. discloses a number of possible solid supports that can be employed with respect to the enrichment channel (See column 6, lines 1-56). Specifically, the reference of Nelson et al. discloses the use of "ion-exchange membranes" (See column 6, lines 37-45). An ion-exchange membrane is charged and can have pores that are larger than the charged analyte that it binds with since it is merely functioning as a support matrix for binding rather than a physical particle filter. As a result, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the optimum material for enclosing the enrichment channel based merely on the specifics of the analyte to be reacted and/or detected in the system. Note while the reference of Nelson et al. does not disclose or mention generating an electric field of the opposite polarity to the membrane, the modified structure would be structurally capable of generating the claimed electric field since the reference discloses the use of electrodes connected to a power supply for generating an electric field between the electrodes. The device is capable of generating an electric field of either polarity between electrodes 60 and 61. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to the charge on the membrane of claims 5-10, based merely on the specific material of the membrane employed, the material will inherently include a positive or negative charge. Additionally, it would have been obvious to one of ordinary skill in the art to provide a

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desired charge for the capture of reaction products as suggested by the reference of Nelson et al. (See column 6, lines 46-53).

With respect to the side channels of claims 6-10, the reference of Nelson et al. discloses the use of side channels (14, 15).

With respect to the electrodes of claims 9 and 10, the reference of Nelson et al. discloses the use of electrodes (60 and 61) with respect to the side channels. As is known in the field of electrophoresis, the voltage applied to the electrodes can be positive or negative based merely on the desired direction of flow. As a result, the electrodes of Nelson et al. are structurally capable of being positive or negative.

With respect to the claimed upstream module of claim 11, it would have been obvious to one of ordinary skill in the art to purify the sample prior to introduction into the microreactor system for the known and expected result of removing any components of the sample which may interfere with the analysis reactions and/or detection.

With respect to the downstream separation module of claim 12, the reference of Wang et al. discloses that it is conventional in the art to provide the protein digested sample of a microfluidic device to a MS for further separation and analysis (See Figure 1 and related text). As a result, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further analyze the reaction products of the device of Nelson et al. using a MS as suggested by the reference of Wang et al.

With respect to the enzyme agent recited in claims 36 and 38, the reference of Wang et al. discloses that the use of an enzyme, trypsin, which is a protease.

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6. Claims 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al.(US 6,007,690) in view of Wang et al.(Rapid Communications in Mass Spectrometry) taken further in view of Kenten et al.(US 7,063,946).

The combination of the references of Nelson et al. and Wang et al. has been discussed above.

While the combined reference suggest the use of a protease enzyme, claims 37 and 40 differ by reciting the use of a phosphatase or sequence-specific cleavage agent.

The reference of Kenten et al. discloses that it is conventional in the art to employ a variety of cleavage agents when analyzing protein samples (See column 15, lines 29-47). The reference lists protease and phosphatase as possible agents.

In view of this teaching, it would have been obvious to one of ordinary skill in the art to determine the optimal cleavage agent to employ based merely on the intended sample to be analyzed and/or peptide sequence to be detected.

Response to Arguments

7. With respect to the rejection of claims 1, 3 and 5-12 under 35 USC 103 over the combination of the references of Nelson et al. and Wang et al., Applicants advance the following arguments:

The reference of Nelson does not teach or suggest the claimed “electric field generating device being capable of generating an electric field of the opposite polarity to said membrane to allow removal of the concentrated analyte from said membrane” (See pages 8-11 of the response filed 9/6/2006).

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In response, the Examiner is of the position that while the reference of Nelson is not operated in the manner as argued by Applicants, the modified device of Nelson is structurally the same as that instantly claimed because the reference discloses the use of electrodes 60 and 61 for generating an electric field. As a result, the pair of electrodes are capable of generating an electric field of either polarity when connected to a power supply. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The device of Nelson functions in a different manner than that of the instant invention. Applicant stresses that the reference of Nelson does not teach or suggest the benefits of concentrating the analytes at a membrane through the application of an electric field and removing the analytes from the membrane by reversing the polarity of the applied electric field (See pages 11-13 of the response filed 9/6/2006).

In response, the Examiner is of the position that the structure of the modified reference of Nelson et al. as discussed in the prior art rejection above is structurally the same as that instantly claimed and would be capable of concentrating analytes as intended by applicants. Note a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The reference of Wang et al. fails to correct for the deficiencies with respect to the reference of Nelson et al. (See page 12-13 of the response dated 9/6/2006).

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In response, the reference of Wang et al. was not relied upon to disclose the claimed porous membrane. Rather the reference was merely recited to address the additional claim limitation of an enzyme positioned within the microchannel device.

The reference of Nelson teaches away from the claimed membrane (See page 13 of the response dated 9/6/2006).

In response, when addressing the membrane limitation of the instant claims, the Examiner did not rely on the disclosure of the embodiment using device 90. The Examiner relied upon a different portion of Nelson et al. which discloses a number of possible solid supports that can be employed with respect to the enrichment channel (See column 6, lines 1-56). Specifically, the reference of Nelson et al. discloses the use of "ion-exchange membranes" (See column 6, lines 37-45). An ion-exchange membrane is charged and can have pores that are larger than the charged analyte that it binds with since it is merely functioning as a support matrix for binding rather than a physical particle filter.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


William H. Beisner
Primary Examiner
Art Unit 1744

WHB

